

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 10, 2010 has been entered.

Applicants' arguments, filed March 10, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

**Claims 1, 6-7 and 14-18 are currently under examination on the merits.**

### ***Information Disclosure Statement***

References previously cited on the information disclosure statement filed June 30, 2009 but not considered have now been considered. All references previously submitted on information disclosure statements have now been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, 6 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of diabetes with the elected species, Compound CGP02-01, does not reasonably provide enablement for making or using the full scope of the compounds claimed in claim 1 or 6 or for the intended uses claimed in claims 16-18 for any compound including the elected species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The enablement of making and using the compounds has been previously addressed in pages 3-4 of the previous office action dated November 10, 2009 and pages 3-5 of the office action dated March 31, 2009 the reasons of which are herein incorporated by reference. Applicant has eliminated from compounds from claim 6, and has eliminated some of the many options from the generic claim 1, however they both encompass many compounds which vary widely from the elected species, which is the only compound that applicant has shown how to make or use. For example, the other compounds in claim 6 vary from the elected species in that they have a different ring structure or have bromine groups off of the benzene ring instead of the methoxy groups. These are reactive groups and would significantly alter the activity of the compound which is hard to predict. The compounds of claim 1 still encompass thousands of possibilities that vary widely in structure and one of skill in the art would not expect them to all have the same effect. Osol et al. (Remington's Pharmaceutical Sciences, Chapter

27, attached) teaches that structural formulas are unpredictable with regards to activity and that drugs which are strikingly similar may have widely differing pharmacologic properties (page 425, column 1, paragraph 1). Thus the activity of these compounds is unpredictable when based only on the activity of one other compound which varies significantly in structure from the others claimed.

Additionally, applicant claims intended uses in claims 16-18, including treatment and prevention of lipid metabolism disorders (claim 16), cardiovascular diseases (claim 17), atherosclerosis, obesity and diabetes amongst others (claim 18). Applicant must enable the intended use of a claim and applicant has now shown how one of skill in the art would make or use any of the claimed compounds, including the elected species to prevent diabetes. Prevention of a condition is unpredictable, and prevention of multiple conditions such as "lipid metabolism disorders" or "cardiovascular diseases" is even more unpredictable and difficult because not all cardiovascular disorders have the same cause or pathology. One of skill in the art would not expect that one compound could prevent all cardiovascular conditions or lipid metabolism disorders. Furthermore, for conditions such as cardiovascular disease and atherosclerosis, prevention is very difficult as evidenced by Yokoyama et al. (2009/0156675 A1) who teaches that many trials have been done to determine if various drugs which shown to be effective in improving these conditions can also prevent them, but the results have not been good and prevention of cardiovascular diseases is difficult (page 1, [0002-0005]). Further, applicant has also not shown how to treat conditions such as epatic steatosis, obesity, cerebral ischemia, hylomicroneamia with even the elected species and they have also

not enabled treatment of any of the claimed conditions with compounds beyond the elected species.

Thus claims 1, 6, 14-18 are rejected for lacking an enabling disclosure.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6-7 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai et al. (US 2003/0105140 A1) already of record, for the reasons set forth at pages 4-6 of the previous office action dated November 10, 2009 as well as

at pages 6-7 of the office action dated March 31, 2009, of which reasons are herein incorporated by reference.

Applicant has amended the scope of the claims, but they all still read upon the elected species and the applicability of the prior art with regards to the elected species is unchanged. Applicant has argued that Cai et al. does not disclose the therapeutic activity of the elected species specifically, since they do not exemplify the elected species but it is encompassed by the generic structure, and that the therapeutic activity of the compound should be considered. Applicant then argues that the activities taught for the other compounds of Cai et al. are different than the activities claimed by applicant. Thus the basis of applicant's argument appears to be that you would assume the compounds of the generic formula would be useful for treatment of cancer but not the conditions that applicant is disclosing and claiming. The prior art is not required to have the same reason for using a composition in order to render the composition obvious or unpatentable. The same composition must necessarily be useful for the same things, and applicant's discovery of a new property or new use for the composition does not render the composition unobvious.

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the

reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." See MPEP 2112.

Applicant has also submitted a declaration under 37 CFR 1.132 by Gerard Marguerie, which shows two compounds of Cai et al. and states that they do not share the claimed activity and then shows other compounds which do not read on Cai et al. at all and states that they also do not have the claimed activity. These compounds all vary significantly from the elected species and one of ordinary skill in the art would not expect all of these compounds to have the same activities. It does not mean that the

elected species, which is in fact taught by Cai et al. does not have this activity and is not evidence of unexpected results. It is noted that the compounds exemplified by Gerard Marguerie vary significantly from the elected species in that they do not have the benzene ring substituted with methoxy and hydroxyl groups, they instead have hetroaryl rings which are very different. The prior art is not required to teach the same activity for a composition claim, the compounds of Cai et al. are only required to have a single activity , which in Cai et al. is treating cancer.

Applicant's arguments have been carefully and fully considered however are not deemed to be persuasive. **The rejection of claims 1, 6-7 and 14-18 is maintained.**

### ***Conclusion***

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 10:30am-7pm Monday-Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/MEGHAN FINN/

Examiner, Art Unit 1629

/Leslie A. Royds Draper/

Primary Examiner, Art Unit 1629